

PERFORMANCE OF JUNCTIONAL TOURNIQUETS IN NORMAL HUMAN VOLUNTEERS

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ABSTRACT

Background. Inguinal bleeding is a common and preventable cause of death on the battlefield. Four FDA-cleared junctional tourniquets (Combat Ready Clamp [CRoC], Abdominal Aortic and Junctional Tourniquet [AAJT], Junctional Emergency Treatment Tool [JETT], and SAM Junctional Tourniquet [SJT]) were assessed in a laboratory on volunteers in order to describe differential performance of models. **Objective.** To examine safety and effectiveness of junctional tourniquets in order to inform the discussions of device selection for possible fielding to military units. **Methods.** The experiment measured safety and effectiveness parameters over timed, repeated applications. Lower extremity pulses were measured in 10 volunteers before and after junctional tourniquet application aimed at stopping the distal pulse assessed by Doppler auscultation. Safety was determined as the absence of adverse events during the time of application. **Results.** The CRoC, SJT, and JETT were most effective; their effectiveness did not differ ($p > 0.05$). All tourniquets were applied safely and successfully in at least one instance each, but pain varied by model. Subjects assessed the CRoC as most tolerable. The CRoC and SJT were the fastest to apply. Users ranked CRoC and SJT equally as

performing best. **Conclusion.** The CRoC and SJT were the best-performing junctional tourniquets using these methods. **Key words:** tourniquets; hemorrhage; resuscitation; groin; inguinal; medical device

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INTRODUCTION

Junctional wounds, which occur at the junction of the torso and appendages, are a common problem in the current war,¹ and junctional hemorrhage is a common cause of death on the battlefield.^{2,3} Indeed, junctional hemorrhage constitutes a major source of potentially preventable deaths.^{4,5} To treat such wounds, junctional tourniquets have been devised that compress peripheral blood vessels, thereby controlling regional blood flow in order to slow or stop exsanguination from the wound. Such hemorrhage control by tourniquet use is intended to be started out of hospital, near the point of injury or during evacuation.^{6,7}

In order to control junctional bleeding and prevent deaths, development led to newly FDA-cleared junctional tourniquets.^{8,9} To date, there has been only one direct comparison of the four junctional tourniquets: a limited, manikin study.³ A similar comparison of the performance of these four junctional tourniquets, but used on normal volunteers has not been conducted or published previously. The military planning committee for combat casualty care research requested such a study to inform tourniquet fielding recommendations. Furthermore, the American College of Surgeon's Committee on Trauma has an External Hemorrhage Control Guideline whose authors specifically mention that junctional hemorrhage control devices were not included in the guideline because of a paucity of human clinical data.¹⁰ The present study provides information relevant to that knowledge gap and to subsequent possible updates of the guideline.

The present study was designed to provide tactical medical personnel and other stakeholders in combat casualty care with a set of data concerning the ranked differential performance of these devices in humans. The objective of the present study was to assess junctional tourniquets for efficacy and safety in normal human subjects.

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METHODS

A U.S. Army Institute of Surgical Research (USAISR) protocol was approved by the U.S. Army Medical Research and Materiel Command Institutional Review Board (Performance of Junctional Tourniquets in Normal Human Volunteers, Study number: H-13-016). This study was conducted in accordance with the approved protocol.

The experimental design of the current laboratory study was a paired design in a time series using normal human volunteers. Sequential use of four models of junctional tourniquets used three times each per subject led to 12 uses per subject.

The junctional tourniquet models were used in accordance with their instructions for use. Three tourniquets were applied on the right inguinal region first, then on the left side, and then again on the right. One model was applied to the umbilicus.

There were 10 subjects and 120 total tourniquet applications. One volunteer was tested at a time, and there was a 5-minute rest period in between each application. All applications for a given subject were conducted on the same day.

There were two tourniquet users; both were investigators and senior military physicians with prior combat experiences as well as operational (prehospital) medicine assignments as line battalion surgeons (team physician internal to an 800-soldier infantry unit). The first user applied the tourniquets to the first subject, and then the second user applied the tourniquets to the remaining 9 subjects. The first user was also the second subject, and the first subject was also the second user.

At the time of the study, only four junctional tourniquets were cleared by the U.S. Food and Drug Administration for inguinal hemorrhage control (Table 1). The tourniquets included the Combat Ready Clamp

(CRoC, Combat Medical Systems, Fayetteville, NC), the SAM Junctional Tourniquet (SJT, SAM Medical Products, Wilsonville, OR), the Junctional Emergency Treatment Tool (JETT, North American Rescue Products, Greer, SC), and the Abdominal Aortic and Junctional Tourniquet (AAJT, previously named the AAT, Abdominal Aortic Tourniquet, Compression Works, Hoover, AL). The inguinal region was the only body area for which all four tourniquets shared an indication; hence, all tourniquets were tested for only the inguinal indication. At the time of the assessment, the point of application for the AAJT for the inguinal indication was at the umbilicus. Tourniquets were opened from packaging, assembled, and ready for use prior to each test.

In addition to height and weight, each subject had a baseline evaluation of distal lower extremity pulse, heart rate, and systolic and diastolic blood pressure to provide a baseline, preapplication status. These measures served as a control for comparison during tourniquet use. The average change from baseline of each individual's physiologic parameters was assessed. The surrogate for bleeding was the presence of a distal pulse detected by hand-held Doppler transducer (Nicolet Vascular Elite Model 100, Viasys Healthcare, Conshohocken, PA), which made an audible pulse sound. The dorsalis pedis artery or the posterior tibialis artery was used for pulse detection. For our purposes, pulse absence represented hemorrhage control. The pulse detection was continued for 60 seconds after the investigator completed tourniquet application and believed he had controlled the hemorrhage. The pulse detection was noted also during the first 15 seconds of control; this was labeled early control and was used to confirm the user's impression whether or not control was attained. Also, during the last 15 seconds of the 60-second period, late control was assessed and used

TABLE 1. Junctional tourniquet traits

| Name Nickname | Combat Ready Clamp | Abdominal Aortic and Junctional Tourniquet | Junctional Emergency Treatment Tool | SAM Junctional Tourniquet |
|-----------------------------|---|--|--|--|
| Maker | CRoC Combat Medical Systems | AAJT Compression Works | JETT North American Rescue Products | SJT SAM Medical Products |
| City, state | Fayetteville, NC | Hoover, AL | Greer, SC | Wilsonville, OR |
| 510(k) date(s) ^a | 8/11/10; 4/29/13 | 10/18/11; 12/6/2013 ^c | 1/3/13 | 3/18/13, 7/24/13 |
| FDA number(s) | K102025; K130482 | K112384, K133029 | K123194 | K123694; K131561 |
| NSN ^b | 6515-01-589-9135 | 6515-01-616-4999 | 6515-01-616-5841 | 6515-01-618-7475 |
| Cost (\$ USD, est. USG) | 654 | 515 | 220 | 292.50 |
| Weight (g) | 799 | 485 | 651 | 499 |
| Cube (L) | 0.8 | 1.4 | 1.6 | 1.5 |
| Indication(s) | Battlefield, difficult inguinal bleeds; axilla bleeds | Battlefield, difficult inguinal, pelvis, axilla bleeds | Difficult inguinal bleeds | Difficult inguinal bleeds; difficult axilla bleeds; pelvic fracture immobilization |

USD, United States dollars; USG, United States Government; FDA, United States Food and Drug Administration.

^a510(k) date is the date when the FDA issued its letter clearing the device for use according to the labeling.

^bNSN, National Stock Number for the federal logistics system.

^cThis was a post-study clearance.

to determine whether or not control was maintained. If the pulse returned late (during the last 15 seconds of the 60-second application), then collateral blood flow appeared to be present as a recurrent pulse detection, as previously implied.¹¹ Swan et al. observed pulse return with pressure point compression but did not evidence whether it was true collateral flow, tiring of the person applying the pressure, or muscular relaxation of the subject, and any or all of these may play a role in pulse return.¹¹

Pain was measured on a visual analog scale. The pain scale was a 100-mm-long line on a piece of paper, the line had no cross-hatch marks, and the left side was the zero point that anchored the line. The subject made a cross mark on the line, which went from the left limit at no pain to the right limit at very severe pain.

Safety and discomfort issues were noted, and the time from initial tourniquet application until a non-measurable pulse occurred was recorded. Subjects could stop testing at any time; for example, if pain was too great, the subject would stop an iteration of testing. Safety was defined as an absence of adverse events (any undesirable sign, symptom, or medical or psychological condition) except that uncomplicated pain that resolved promptly after devices use was not considered an adverse event even if the subject stopped the test iteration. During and after each test iteration, subjects were assessed for complications like neuropraxia.¹¹

After data collection was complete, the two investigators who applied the tourniquets ranked the devices on the basis of their subjective impressions of tourniquet performance.^{11,12} The rank, R , was a whole number ascribed by a user to a given device ($R = 1$, best; $R = 4$, worst). The rank was converted into a score (score = $5 - R$). The users' scores for each device were summed. Similarly, subjects ranked performance subjectively. For 10 subjects, the best possible score would be 40 and the worst possible score would be 10.

Statistical testing included repeated measures analysis of variance (ANOVA) to see if any device was different from the others (SAS Institute, Cary, NC). The ANOVA was adjusted using Tukey's honestly significant difference (HSD) test for pairwise comparisons; when ANOVA was statistically significant or was nearly statistically significant ($p \sim 0.06$) we made pairwise comparisons. We used the chi-squared test or Fisher's exact test for analysis of categorical data. Descriptive statistics were used to portray results. Significance for results was established when p -values were less than 0.05.

RESULTS

The study group was constituted with 10 normal volunteers recruited from the workplace of the inves-

tigators (10 males, aged 42–60 years; average age, 51 years). The average height and weight were 71 inches and 189 pounds, respectively. The body mass index averaged 26.5. At baseline the average supine systolic and diastolic blood pressure and heart rate were 124 mmHg, 74 mmHg, and 62 beats per minute, respectively. At baseline the average visual analog scale for pain was 0 mm on a scale of 100 mm.

Effectiveness Results

All four models of junctional tourniquet were made to be effective at least once by the two tourniquet users, but the effectiveness percentage varied by model (Figure 1). The most effective junctional tourniquet tested in the present study was the CRoC, and the least effective junctional tourniquet was the AAJT because subjects stopped the iteration of use early in 73% of tests due to pain. The effectiveness of the AAJT was 100% for 1 subject, 67% for another subject, 33% for 3 subjects, and 0% in the remaining 5 subjects. The subject with 100% effectiveness was the first subject assessed.

Effectiveness percentages were measured in terms of early effectiveness, which was determined in the first 15 seconds of use out of a total of 60 seconds, and late effectiveness, which was determined based on the last 15 seconds of use. For each of the four models, differences for early and late effectiveness were not statistically significant. Late effectiveness may have indicated collateral flow or skeletal muscle relaxation of the subject; collateral flow through uncompressed arteries may allow arterial flow to distal arteries which are networked, thereby allowing retrograde blood flow through other arteries back up toward the occlusion, allowing, for example, Doppler detection of a returned pulse at the posterior tibial artery near the ankle. The AAJT, which aims to compress the distal aorta and adjacent blood vessels when used over the umbilicus where there appears to be no effective collateral vessels, had no change in early or late effectiveness. The AAJT was significantly less effective than the other 3 devices for both early and late effective percentages, with $p < 0.0001$ in all cases. None of the other devices had significantly different effective percentages when compared to each other.

By ANOVA, the differences in time to effectiveness were not statistically significant by model of junctional tourniquet or side of use ($p = 0.0601$ and 0.0747 , respectively; Figure 2). In pairwise comparisons, statistically significant differences were noted between the CRoC and the JETT ($p = 0.011$), and the CRoC and the AAJT ($p = 0.045$; $p > 0.2537$ for all others). The AAJT had only 8 of 30 (27%) uses where it was effective, as 22 of 30 (73%) uses were terminated for pain before the tourniquet was effective; therefore, the AAJT times were shorter.

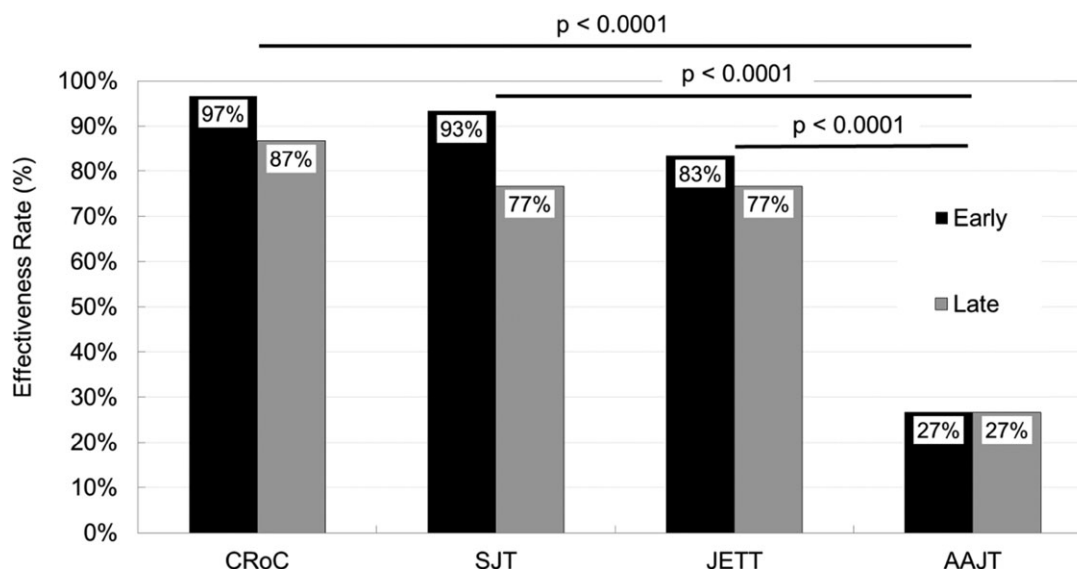


FIGURE 1. The junctional tourniquet effectiveness percentages varied by model. The CRoC, the SJT, and the JETT had the highest effectiveness percentages; their differences were not statistically significant. Tourniquet use was for 60 seconds; early effectiveness was during the first 15 seconds, and late effectiveness was during the last 15 seconds. For each of the four models, differences for early and late effectiveness were not statistically significant.

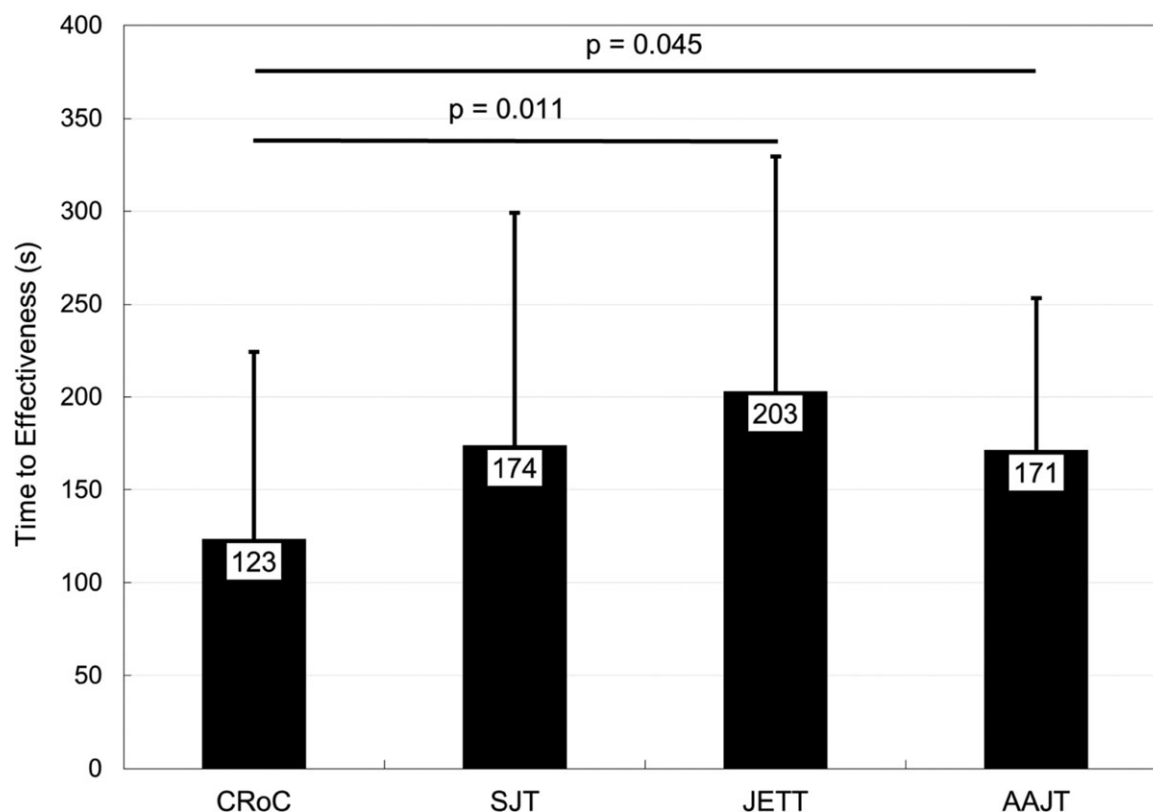


FIGURE 2. By ANOVA, there were no differences in time to effectiveness by model of junctional tourniquet ($p = 0.0601$). The fastest tourniquets to use were the CRoC and the SJT. In pair-wise comparisons, significant differences were noted between the CRoC and the JETT ($p = 0.011$), and the CRoC and the AAJT ($p = 0.045$; $p > 0.2537$ for the others). The AAJT had only 8 of 30 uses where it was effective as 22 of 30 uses were terminated early for pain; therefore, the AAJT times are shorter than expected. Numbers within columns represent the average time to effectiveness. Vertical bars represent standard deviation.

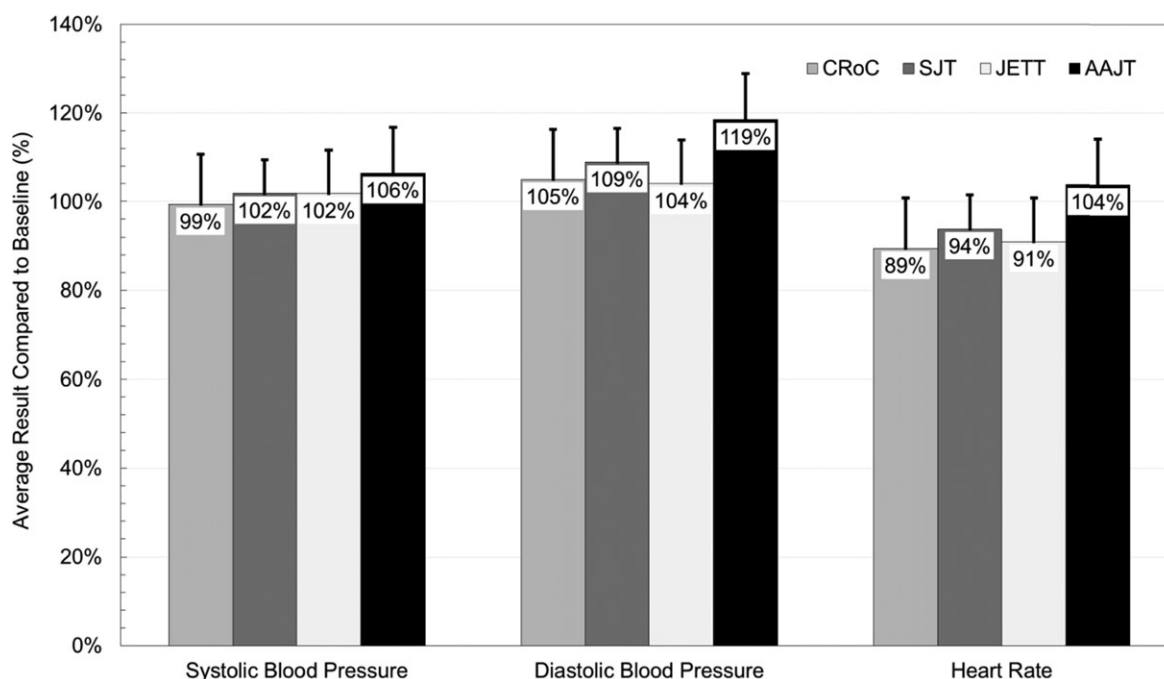


FIGURE 3. The average changes in physiological parameter varied by model of junctional tourniquet. The change was of each subject's iteration indexed to their baseline, and the average was made of all subjects and all iterations. The vertical bars represent standard deviation.

Physiological Results

When indexed to baseline for each subject, the average change in the physiological parameters of heart rate, systolic blood pressure, and diastolic blood pressure for each subject varied during junctional tourniquet use (Figure 3). Heart rate responses varied by model of tourniquet ($p < 0.0001$). Three of four tourniquet models were associated with a decreased average heart rate, but the AAJT was associated with an increased average heart rate. In pairwise analysis using the Tukey adjustment, the change in heart rate for AAJT use differed from the other three models ($p < 0.0001$). Other than for AAJT, no pairwise comparison among models was significant ($p > 0.3381$). Additionally, application of tourniquets to either left or right sides produced comparable changes in heart rates (data not shown; $p = 0.4936$).

Systolic blood pressure for AAJT use was higher than that from CRoC use ($p = 0.0137$). No other pairwise comparison among models was different ($p > 0.1138$ for all others). Additionally, left and right side applications were associated with comparable changes in systolic blood pressure changes (data not shown; $p = 0.1146$).

Diastolic blood pressure varied by model of tourniquet. Three of four models resulted in comparable modest increases in average diastolic blood pressure, whereas use of the AAJT produced an increase that averaged 2.6-fold greater than use of other tourniquets (Figure 3; $p \leq 0.03$). The other three devices were not different among themselves ($p \geq 0.31$). Additionally,

when tourniquets were applied to the left side, diastolic blood pressure changes were 2.3 mmHg higher than when applied to the right side (data not shown; $p = 0.0059$).

Safety Results

All 120 tourniquets uses were conducted within the parameters of safety as defined by the absence of adverse events; all four tourniquets were equally safe, but comfort varied by model. Subjects measured pain of the AAJT as severe pain at an average of 76 mm on a 100-mm scale (Figure 4). The AAJT was the most uncomfortable junctional tourniquet, and its subjective pain index was greater ($p < 0.0001$) than those of the other three devices, which among themselves did not differ ($p > 0.1662$). Additionally, application of tourniquets on left and right groin sides did not differ for pain measurements ($p = 0.49$).

Among the four junctional tourniquets, the AAJT was associated most often with minor symptoms, such as panting and difficulty in breathing normally. Such symptoms were likely due to mechanical blockade of the fullest extent of inspiration while the abdomen was compressed. It was also frequently associated with abdominal pain, trunk tightness, and occasionally with nausea and lightheadedness.

Subjectively Ranked Performance Results

Subjects ranked (subjective performance) the CRoC first ahead of the other devices (Figure 5; $p \leq 0.03$), and

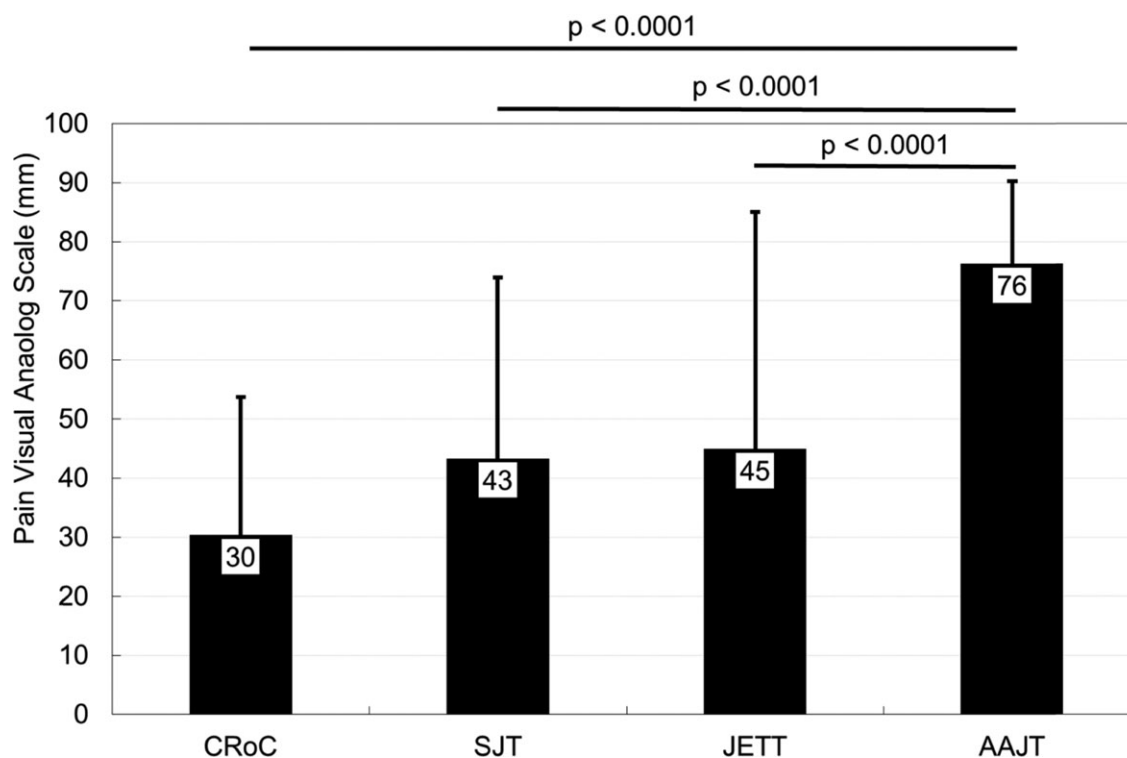


FIGURE 4. The average pain scores varied by model of junctional tourniquet. The AAJT was the most painful junctional tourniquet ($p < 0.0001$); the other three devices were not different from each other ($p > 0.1662$ for all three). Note that the rank order from least pain to most pain was the same order as the subjects' ranking of performance from best to worst (Figure 5).

the AAJT was ranked last by 9 of 10 subjects compared with all other models (Figure 5; $p \leq 0.0002$). Rankings of the SJT and the JETT did not differ ($p = 0.9887$). The CRoC indicated some variability in preference, while the AAJT had little variability.

The two users ranked the CRoC and SJT equally best; each user picked one as best and the other as second best so these two models tied overall at 7 points. Both users ranked the AAJT as worst, but both users had also been subjects so the experience as user and subject

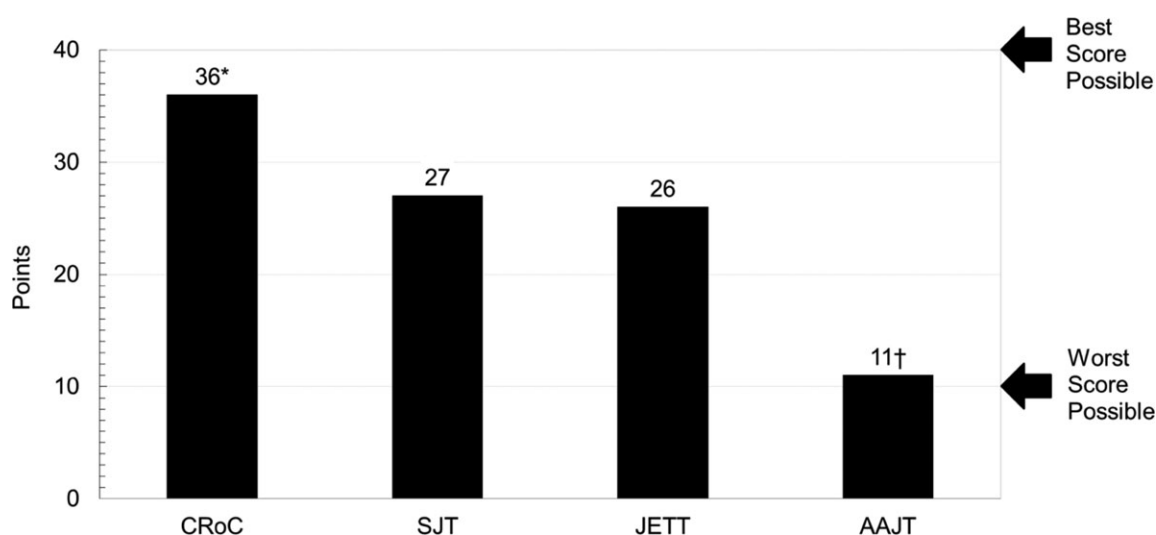


FIGURE 5. The subjects on whom junctional tourniquets were used subjectively ranked performance by model; the rankings were summed as a number of points. Performance differed by model (ANOVA, $p < 0.0001$). The CRoC ranked best in this subjective performance (maximum $p = 0.03$). The SJT and the JETT points did not differ ($p = 0.99$). The AAJT performed the worst among all models ($p \leq 0.0002$). Note that the rank order of performance from best to worst was the same order as the subjects' ranking of least pain to most pain (Figure 4). Numbers above columns are the average number of points that represent subjective performance.

may not have been wholly separable during ranking which was after both use and subjection.

DISCUSSION

The first major finding of the present survey was that all four junctional tourniquets could be effective with varying degrees of manipulation by users, but the effectiveness of these tourniquets varied from 27 to 97%. The most effective junctional tourniquet tested in the present study was the CRoC. Low effectiveness for the AAJT was associated with such severe pain that subjects stopped the iteration in 73% of its uses. Early effectiveness during the 60 seconds of use was higher than late effectiveness percentages for three devices, and collateral flow or skeletal muscle relaxation may have played a role. The effectiveness percentage of the AAJT, which aims to compress the blood vessels where there appears to be no effective collateral vessels, exhibited no difference between early and late effectiveness percentages. The issue of whether or not a returned pulse necessarily will mean failure of hemorrhage control is an open question as retrograde pulsation by collateral flow may have a limited pressure head and may limit the degree of distal ischemia.¹¹

The second major finding of the present study was that there were no safety issues in terms of adverse events during the brief use in the present study; however, pain associated with application of the AAJT was enough for most subjects to stop the tests. Except for pain, all four devices were equally safe as defined in this limited study with short durations of tourniquet use. Comfort varied by model, and the most comfortable junctional tourniquet was the CRoC; it produced mild discomfort at an average of 30 mm on a 100-mm scale. The most uncomfortable junctional tourniquet was the AAJT; it caused severe pain at an average of 76 mm. Additionally, limiting the meaning of the safety results are the low percentages of AAJT success. Since so few subjects tolerated successful use, the scope of use of the AAJT was restricted; this restriction limits the assessment of its safety. Notably, the pain score rank order from least pain to most pain was the same order as the subject ranking of best performance from best to worst.

The first minor finding of the present study was that physiological changes in blood pressure and heart rate were associated with the four junctional tourniquets, and these physiological changes appeared to differ by model. These physiological changes among the models of junctional tourniquets may be secondary to differences in design traits and application interface that is inherently different in each model of tourniquet. For example, the compression of the AAJT upon the aorta and inferior vena cava was expected to have the largest effect on the physiological parameters, and this effect was confirmed for all three physiological param-

eters measured. The body surface area compressed by the AAJT is the largest of the four tourniquets, and the targeted blood vessels are the largest in lumen diameter, cross-sectional area, and blood flow.

The second minor finding was that the ranked performance results indicated that the users and subjects assessed the best junctional tourniquet in the present study differently. The subjects ranked the CRoC as the best. Users equally ranked the CRoC and SJT as best or as second best such that they both tied overall. Nine of 10 subjects and both users ranked the AAJT as worst.

A strength of the present study is that it offers a direct comparison of the four currently FDA-cleared junctional tourniquets by assessors who are neither financially nor academically associated with the makers. This strength fills a specific knowledge gap for junctional tourniquets on their differential performance by model.

Limitations of the present report are numerous. The design of the study was constrained by a common FDA-cleared indication, inguinal bleeding; thus, only this body region was evaluated. The axilla and other areas were unassessed, although two of the four share the axilla indication. At the time of the study, the AAJT was not FDA-cleared for groin use except through periumbilical compression of the distal aorta (which made such use bilateral). Since then, the AAJT received FDA clearance for direct, unilateral groin application. The two compression sites in question, periumbilical and groin, for the AAJT that can control inguinal blood flow appear to have substantially different comfort levels as the groin placement is more tolerable (M. Lyon, et al., research presentation, Efficacy of the Abdominal Aortic Tourniquet device for the control of axillary and femoral artery blood flow, Special Operations Medical Association Scientific Assembly 2013, Tampa, FL). Since the present study preceded direct inguinal indication FDA clearance, the study design may be biased against the AAJT. We studied a very narrow patient population (all male, age range only 42–60 years, and no obese subjects); for military applicability a younger patient population with some women included would be ideal and for civilian use a much broader population may be considered for further study.

There are many directions for further research. This differential performance assessment of junctional tourniquets may offer a comparison from which other investigators may model their own studies, for stakeholders to decide fielding issues, or for medics to field test tourniquets. Combat Lifesavers, Medics, or Special Operations Paramedics may be better surrogates of the intended battlefield user than the two physicians who were users in the present study. Tests among the military services of other nations are sought. Axillary testing would be useful, and reassessment of the AAJT is needed since its recent FDA clearance and labeling change. The phenomenon of apparent

collateral flow needs to be understood better; currently, the phenomenon is rarely mentioned in reports on hemorrhage control interventions. Study of device users who also serve as subjects was not ideal due to subject–user confounding; further work may seek to separate roles.

CONCLUSION

In normal human volunteers new evidence of junctional tourniquet performance for difficult inguinal bleeding indicates that the Combat Ready Clamp and SAM Junctional Tourniquet performed well.

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